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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/781,843

02/20/2004

Munetetsu Tei

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04/25/2005

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EXAMINER

AFREMOVA, VERA

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/781,843

**Applicant(s)**

TEI, MUNETETSU

**Examiner**

Vera Afremova

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Claims 1-54 are pending and subject to restriction requirement:

#### *Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-36, drawn to an antitumor and antiviral medication comprising activated lymphocytes having heat shock proteins, classified in class 424, subclass 93.71, for example.
- II. Claims 37 and 38, drawn to an antitumor medication consisting of reserpine derived from *Rauwosa serpentina*, classified in class 424, subclass 725, for example.
- III. Claims 39-50, drawn to a method for producing antitumor and antiviral medications by activating and heating lymphocytes, classified in class 435, subclass 325+, for example.
- IV. Claims 51 and 52, drawn to a method for producing antitumor and antiviral medication by treating activated lymphocytes with galenical extract of crude drugs, classified in class 435, subclass 372, for example.
- V. Claim(s) 53, drawn to a method for producing antitumor and antiviral medication by heating lymphocytes together with galenical extract, classified in class 435, subclass 375, for example.
- VI. Claim(s) 54, drawn to a method of administering antitumor and antiviral medication, classified in class 424, subclass 9.1, for example.

The inventions are distinct, each from the other because of the following reasons:

Art Unit: 1651

Inventions I and II are drawn to two clearly distinct products such as cellular and chemical products that are lymphocytes cells (group I) and chemical compound or plant extracts (group II).

The instant application contains claims drawn to several methods of making different products (groups II, IV and V). The methods are distinct from one another as claimed because they recite different active steps of activating or treating lymphocytes with various inducing agents at various conditions that lead to possession of different final compositions or products. Or, in the alternative, the product of Group I can be made by several materially different processes as presently claimed.

Inventions of the group I and of the groups III-V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.0549). In the instant case the Group I product comprising compositions with activated lymphocytes can be made by another and materially different process of culturing with antibody, for example: abstract of JP 3-080076 (IDS reference).

Inventions of the Group I and of the Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case, the process for using anti-tumor or

Art Unit: 1651

anti-viral medications with stress proteins having molecular weight of 70 kDA can be practiced with another materially different product derived from genetically engineered expressions system including microbial cells, for example: see abstract US 5,891,653 (IDS reference).

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or make obvious the any of the other groups. For these reasons restriction for examination purposes is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Art Unit: 1651

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

April 19, 2005

A handwritten signature in black ink, appearing to read 'V. Afremova', with a long horizontal flourish extending to the right.

VERA AFREMOVA

PRIMARY EXAMINER